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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,949	10/04/2004	Gerardo Perez-Camargo	115808-001	3101

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
10/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/509,949	PEREZ-CAMARGO ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 29-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 29-56 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Applicant is reminded that the office has not received IDS as of this date.

Claims 29-56 are pending in this Application, claims 29-56 will be prosecuted on the merits.

DOUBLE PATENTING

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 29-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48-60 of copending Application No. 10/510126. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially identical nutritional management regimens with an intestinal mucosa function-promoter and also pancreatic function promoter and/or liver function promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improved body condition, improved muscle tone and improved skin and coat does not reasonably provide enablement for any or all kinds of benefits as claimed in independent claim 29. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d

1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

A method of providing a pet with a benefit relating to an effective assimilation of a lipid or lipid fraction comprising the steps of administering to the pet an edible composition comprising a pancreatic function promoter and a promoter selected from the group consisting of a liver function promoter and an intestinal mucosa function-promoter.

(2) The state of the prior art:

The prior art teaches gastrointestinal intolerance and improve, promote or maintain intestinal functions which are characterized as improved body condition. Prior art does not teach any kind of benefit as claimed. (US 6,471,999 and WO 02/15719).

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

The unpredictability of the art is very high.

(5) The breadth of the claims:

The claim is very broad. The term benefit encompasses any/every/ all kinds of benefits associated with the claimed composition, which is not defined by the specification, and thus a

skilled artisan would have to perform undue experimentation to obtain any/every or all kinds of benefits associated with the claimed composition.

(6) The amount of direction or guidance presented:

The specification does not provide guidance with respect to claiming any or all or every benefit associated with the claimed composition. A disclosrue should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724).

(7) The presence or absence of working examples:

There are insufficient working examples to show that the claimed composition will provide all/every /any benefit relating to an effective assimilation of lipid.

(8) The quantity of experimentation necessary:

A skilled artisan will undergo a burden of performing undue experimentation in order to practice the invention commensurate with the scope of the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 33, 38, 39, 42 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "general health aspects ", it is not clear which general health aspect is the Applicant referring to. The metes and bounds of the claim are not defined. The phrase "pet to owner relationship "is a relative term and is indefinite as it is not clear what kind of relationship is the applicant referring to. The claim is therefore indefinite. Claim 38 and claim 53 recite the limitation "younger look". The term is a relative term and is thus indefinite. The term glutathione promoter does not define metes and bounds of the claim, therefore makes the claim 42 indefinite. The phrase "predetermined directions" is indefinite in claim 39, it is not clear what the predetermined directions are referring to. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 29-56 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,471,999 in view of US 5,290,571 ('571) or US 5,451,412 ('412) and further in view of Hevia (US 2006/0052454 A1).

'999 teaches a pet milk powder as nutritional milk that results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a

specific aspect which comprises lactose (of micro-organism origin), lactase, taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26). '999 teaches including an alkali in the milk-based powder, which slows the pH, drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein (Intestinal mucosa function-promoter) and further supplemented with taurine (liver function promoter) and a probiotic micro-organism (pancreatic function promoter) which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14). '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36). Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats. '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teaches omega fatty acids such as soybean oil and in Examples 1-2 (col. 3, lines 15-20).

'999 does not teach glutathione. However, 571 or 412 teach glutathione.

'571 or '412 teach a composition of whey protein concentrate (abstract). '412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals.

'571 teaches that a suitable source of whey protein is known by the trademark

PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41).
Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function promoter. '571 teaches that glutathione GSH promotion is a major function of the whey protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed with egg white protein (col. 4, lines 39-46). '571 teaches that the object of the invention is to provide a method for increasing the concentration level of glutathione in the organs and enhancing resistance to bacterial infection of mammals through the use of w.p.c, via oral administration (col. 10, lines 46-57). '571 also teaches inclusion of vitamins B1 and B2 with w.p.c. (claim 1-3, col. 11, lines 55-57).
The references do not teach lipid assimilation, however, Hevia teaches lipid digestion due to bile salts which are emulsifying agents and emulsifiers are claimed as liver function promoter.
It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate emulsifying agents such as bile salts to help in lipid digestion and assimilation because emulsifying agent helps in lipid digestion. A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter in order to help in lipid assimilation with a reasonable expectation of success.

10. Claims 29-56 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. Fuchs et al WO 02/15719 ('719) in view of US 5,290,571 ('571) or US 5,451,412 ('412) and further in view of Hevia (US 2006/0052454 A1).

'719 discloses a method of treatment which comprises administering an effective amount of the composition which contains whey protein (an intestinal mucosa function promoter according to applicant) to improve, promote, maintain intestinal function and mucins a patient or companion animal (abstract, claims 1-2 and 14- 20, pg. 6 lines 5-10; pg. 12 lines 3-21). Example 4 teaches a nutritional supplement comprising whey protein and probiotic bacteria. '719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10). Whey protein is taught by applicant to be a fat transportation aid agent and carrier (instant spec pg. 10, 13-20). , '719 also teaches including a prebiotic (claim 13, pg. 5, lines 27-30). '719 teaches including taurine and vitamins (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29), '719 teaches a lipid source including omega-3 fatty acids (abstract, claim 1). , '719 teaches a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2).

'719 does not teach glutathione. However, 571 or 412 teach glutathione. However, '571 or '412 teach a composition of whey protein concentrate (abstract). '412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals. '571 teaches that a suitable source of whey protein is known by the trademark PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41). Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function promoter. '571 teaches that glutathione GSH promotion is a major function of the whey

protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed with egg white protein (col. 4, lines 39-46). '571 teaches that the object of the invention is to provide a method for increasing the concentration level of glutathione in the organs and enhancing resistance to bacterial infection of mammals through the use of w.p.c, via oral administration (col. 10, lines 46-57). '571 also teaches inclusion of vitamins B1 and B2 with w.p.c. (claim 1-3, col. 11, lines 55-57). The references do not teach lipid assimilation, however, Hevia teaches lipid digestion due to bile salts which are emulsifying agents and emulsifiers are claimed as liver function promoter. It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate emulsifying agents such as bile salts to help in lipid digestion and assimilation because emulsifying agent helps in lipid digestion. A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter in order to help in lipid assimilation with a reasonable expectation of success.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S. Kishore, PhD
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Snigdha Maewall

Art Unit

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